**MARIAN UNIVERSITY**

**For IRB Use**

Protocol Number:

**INSTITUTIONAL REVIEW BOARD**

**Biomedical Research Subcommittee**

**Application to conduct Human subjects research**

**Submit completed Application to the Chair of the Biomedical Research Subcommittee**

**mu.irb.brs@marian.edu**

Principal Investigator (P.I.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor (if student P.I.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Office Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-Mail \_\_\_\_\_\_\_\_\_\_\_\_\_

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Mailing Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Project\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Planned Project start date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expected end date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Submission date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ The project is: New \_\_\_\_\_ Continuing \_\_\_\_\_ (Protocol#\_\_\_\_\_\_\_\_\_\_\_)

\* To maintain continuing approval for projects that last more than one year, the investigator must submit a continuing application at least one month prior to the yearly expiration date.

Project type: Non-funded (or student) research \_\_\_\_\_\_\_ Externally funded \_\_\_\_\_\_\_

Supporting agency (if any) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature of Primary Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Co-Investigator(s) Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Faculty Advisor (if applicable) Date

INSTRUCTIONS: All responses must be typed. If needed, reformat the page to accommodate your response or continue each response on additional pages.

The following items should be included in the application:

□ Background (current state of knowledge)

□ Hypothesis

□ Novel aspect of investigation and impact on current knowledge/practice

□ Detailed description of participants (See #1 below)

□ Study Protocol (See #2 Below)

□ ANY potential risk – (See #3 below)

□ Consent Form

□ Surveys and questionnaires

□ Proposed study subject recruitment advertisements

□ Any other materials that would aid in review of the application.

1. **Participants:** Include a discussion of the characteristics, number, and any payment of participants. Explain the participant selection process and how you will initially contact potential participants. If you will be working with participants from another institution or organization, attach documentation of that agency’s permission for you to do so and any pertinent regulations from those agencies. If minor children or dependent parties are to take part in the research, attach a parent/guardian information letter. If you will be working with participants from vulnerable populations (as defined in 45 CRF 46 Subparts A-D), please discuss how you will protect those participants.
2. **Method or Procedure**: Describe the way in which data will be collected from human subjects, including where the study will take place, who will collect data/samples, length of participation, what data will be recorded and how. List and describe any apparatus/medical devices that will be used. Attach copies of any survey or interview questions to be used. Describe how participants will be provided debriefing about the study and an opportunity to obtain further information about the study outcome. If deception is used, provide a rationale and a proposed debriefing report (see Attachment 5: Template for Debriefing When Research Involves Deception).
3. **Assessment of risk**: Determine if participants are at more than minimal risk of harm including, but not limited to, physical, psychological, social, financial, legal, or political harm. Minimal risk is understood to mean “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR 46. 102). (This includes research involving deception of participants). Describe procedures (such as informed consent) that will be used to minimize potential risks to participants. If participants are at greater than minimal risk, responses to Attachment 3: Additional information for Full Review must be included in this application.
4. **Informed consent from participants**: Who will obtain informed consent? Where will consent forms be stored? [Consent forms must be stored separately from data collected for the study.] Attach the full written informed consent form (Expedited or Full Review). Please see the guidelines for informed consent (Attachment 4) to be sure you include all elements of consent.
   1. **Confidentiality**: Describe procedures to be used to maintain confidentiality, including who will have access to identifying information, where data will be stored, when data will be destroyed, and, in the event that findings are published or made public, how participants’ identities will be masked. [Data must be stored under lock and key or in a password-protected computer.]
   2. **Privacy:** Participants must be provided with freedom from public scrutiny, observation, or intrusion. Describe procedures to be used to protect participants’ privacy during the conduct of the study.

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**Attachment 1: Definition of Research and Human Subject**

What is Research?

Research is the systematic and diligent inquiry into a subject in order to discover or revise facts, theories, concepts, or the general body of knowledge that pertains to that subject. For inquiry to be deemed research, it is expected that the final goal or outcome is to disseminate the findings of the project via publication, presentation, or some other form of public dissemination. It is the potential distribution of findings/information that is crucial.

What is a Human Subject?

1. According to the U.S. Department of Health and Human Services:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention or interaction with the individual, or

(2) identifiable private information. (15 CFR 27.102(f))

1. According to FDA regulations covering research with pharmaceuticals and medical devices: "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

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**Attachment 2: Definition of Review Categories**

Exempt Review: Research involving no or minimal risk and in which the only involvement of human participants will be in one or more of the following categories:

1. Research conducted in established educational settings, such as that measuring the

effectiveness of teaching techniques or involving educational tests (cognitive, aptitude,

diagnostic, achievement) if the information cannot be linked to the participant.

1. Research using survey or questionnaire procedures providing the responses are not linked

to the participant, and responses do not place the participant at risk of criminal or civil

liability or constitute damage to the participant’s reputation or employability.

1. Research involving observation of public behavior, provided that the participant's

behavior is not linked to their identity, and that these observations do not place the

participant at risk of criminal or civil liability or constitute damage to the participant's

reputation or employability.

4. Research involving the collection or study of existing data, documents, records,

pathological specimens, or diagnostic specimens, provided these sources are publicly available and the data is recorded in such a manner that the individual participants cannot be identified.

Expedited Review: Research involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the following categories:

1. Voice, video, digital, or image recordings made for research purposes, such as

investigations of speech defects.

1. Research on group or individual behavior or characteristics (including, but not limited to, research on perception, cognition, motivation, communication, cultural beliefs, and social

behavior) or research employing survey, interview, oral history, focus group, program

evaluation, human factors evaluation, or quality assurance methodologies.

1. Prospective collection of biological specimens for research purposes by noninvasive

means. Examples: a) hair and nail clippings in a nondisfiguring manner; (b) deciduous

teeth at the time of exfoliation, or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing; (j) sputum collected after saline mist nebulization.

1. Recording of data from participants 18 years or older using noninvasive procedures (not involving general anesthesia or sedation) routinely used in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging,

doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength

testing, body composition assessment, and flexibility testing where appropriate given the

age, weight, and health of the individual.

1. Collection of blood samples by finger stick, ear stick, heel stick, or venipuncture from

a) healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the

amount drawn may not exceed 550 ml in an 8-week period and collection may not occur

more frequently than 2 times per week; or b) other adults and children under the age of

legal consent, considering the age, weight, and health of the participants, the collection

procedure, the amount of blood to be collected and the frequency with which it will be

collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or

3 ml per kg in an 8-week period and collection may not occur more frequently than 2

times per week.

6. Collection of both supra- and subgingival dental plaque and calculus, provided the

procedure is not more invasive than routine prophylactic scaling of the teeth and the

process is accomplished in accordance with accepted prophylactic techniques.

7. Study of existing data, documents, records, pathological specimens, or diagnostic

specimens that have been collected or will be collected solely for nonresearch purposes

(such as medical treatment or diagnosis).

8. Continuing review of research previously approved by the convened IRB where a) the

research is permanently closed to the enrollment of new participants or all participants

have completed all research-related interventions or the research remains active only for

long-term follow-up of participants; b) where no participants have been enrolled and no

additional risks have been identified; or c) where the remaining research activities are

limited to data analysis.

1. Research on drugs for which an investigational new drug application (21 CFR Part 312)

is not required.

1. Research on medical devices for which (I) an investigational device exemption

application (21 CFR Part 812) is not required; or (ii) the medical device is

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

1. Continuing review of research, not conducted under an investigational new drug

application or investigational device exemption where the two previously listed

categories do not apply but the IRB has determined and documented at a convened

meeting that the research involves no greater than minimal risk and no additional risks

have been identified.

Full Review: Any research that involves more than minimal risk to participants, including…

1. Research that involves deception of participants.
2. Research that involves the manipulation of participants’ behavior, with or without the

participants’ knowledge.

1. Research that involves new and/or untested procedures.
2. Research that involves protected or vulnerable populations.

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**Attachment 3: Additional Information Required for Full Review of Research Involving More Than Minimal Risk to Participants**

Please answer the following questions for all appropriate categories involved in your research.

Risk

For research in which the possibility of injury is greater than minimal:

1. Identify and describe in detail the possible risks, including: physical/physiological (immediate and future), psychological, or social injury, to which participants may be exposed.

2. Explain how the importance of the knowledge gained from this research combined with the benefits for participants or society justifies the possible risks to the participants stated above. Discuss any alternative ways of conducting this research that would present fewer risks to the participant, and explain why the method you have chosen is superior.

3. Explain fully how the rights and welfare of participants at risk will be protected (e.g., equipment closely monitored, medical exam given prior to procedures, psychological screening of participants, etc.)

INTERVENTIONS:

Medical Equipment

For research in which the participants will be in contact with any mechanical, electronic, magnetic, wave energy, or other equipment which might put research subjects at risk of accidental harm or injury, should there be a mechanical failure in the equipment.

1. Identify and describe in detail the equipment to be utilized and the exact location. Use manufacturer’s name and serial numbers, and submit copies of manufacturer's literature on the equipment when available.
2. Identify and describe in detail how the participant will interact with the equipment.
3. Indicate the names and qualifications (with regard to the safe use of the equipment) for all individuals authorized to use the equipment.
4. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the equipment.

Pharmaceuticals

For research in which the participants will be provided pharmaceuticals as part of the protocol, whether the subject of the research study or not, which might put research subjects at risk of accidental harm or injury, should be listed as describe below.

1. Identify and describe in detail all pharmaceutical agent/s to be utilized during the study, include dose and mode of delivery. Use manufacturer’s name and generic name, and submit copies of manufacturer’s literature on the pharmaceutical when available. If it is an experimental pharmaceutical please provide full FDA information.
2. Identify and describe in detail how and when the participant will receive the pharmaceutical.
3. Indicate the names and qualifications FDA numbers for all individuals authorized to administer pharmaceuticals.
4. Indicate in detail specific steps that will be taken to assure the dosage and administration of all pharmaceuticals.
5. List in detail foreseeable risks associated for each pharmaceutical including incidence data.

Psychological or Physiological Intervention

For research in which the participants will be exposed to any psychological intervention, such as deception, contrived social situations, manipulation of the participant’s attitudes, opinion or self-esteem, psychotherapeutic procedures, or other psychological influences, or in which the participant(s) will be exposed to any physiological treatments or interventions upon the body by mechanical, electronic, chemical, biological or any other means.

1. Identify and describe in detail the psychological intervention (or manipulation) and the means used to administer the intervention.
2. Identify and describe in detail the behavior expected of participant(s) and the behavior of the investigator during the administration of the intervention.
3. Describe how data resulting from this procedure will be gathered and recorded.
4. Identify anticipated and possible psychological, physiological, or social consequences of this procedure for the participant(s).
5. Indicate in detail specific steps that will be taken to assure the proper operation and maintenance of the means used to administer the intervention. For all equipment used, the questions regarding equipment above must be answered.
6. For research involving deception, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.
7. For research involving psychological intervention, describe in detail the plan for debriefing participants.
8. Indicate the investigator's competence and identify her/his qualifications, by training and experience, to conduct this procedure. Give name, title, academic affiliation and program, an address, and telephone number of the individual(s) who will supervise this procedure.
9. Describe your plan for safeguards against possible psychological distress among study participants.

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**Attachment 4: Template for Informed Consent Form**

**Instructions to PI:**  In order to qualify under review of the Marian University Institutional Review Board your informed consent form must contain all of the following elements:

I. **Introduction** that includes:

* 1. A statement that the study involves research
  2. The purpose of the research
  3. The duration of the individual’s participation
  4. The procedures to be followed
  5. Which procedures are experimental

II. **Disclosure of Risks and Benefits** that includes:

* 1. A description of any foreseeable risks or discomforts to the participant
  2. A description of any anticipated costs to the participants (e.g. child care, transportation etc.)
  3. A description of anticipated direct benefits to the participants or to others. If there are no direct benefits the investigator should tell participants what he or she hopes to learn from the research, how that knowledge will contribute to the field of study or may benefit others.
  4. A disclosure of any alternative procedures or treatments that may be advantageous to the participant.

III. **Explanation of Safeguards** including:

* 1. An explanation of how the investigator will maintain confidentiality of records.
  2. A full disclosure of any state-mandated reporting requirements, such as suspicion of child abuse, clear and present danger, neglect or harm to others, when warranted by the topic under investigation.
  3. When more than minimal risk has been identified there must be a description of emergency response/treatment available to address any injury/illness and a statement of who has financial responsibility for payment for treatment.
  4. An explicit statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits and that the individual may discontinue participation at any time without incurring negative consequences, other than discontinuation of experimental therapies or treatments. Furthermore it must be explicitly stated that participants may choose not to answer certain questions or complete specific tasks.
  5. Full disclosure of how discontinuation will affect compensation if this is relevant.

IV. **Contact Information** including:

1. Full contact information of study coordinator and an investigator participating in the study, so the participant may discontinue the study at any time or have their questions answered by a person qualified to answer technical questions they may have about the study.
2. Full contact information and procedures to obtain treatment if injury should occur as a result of participation in the study.

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**Attachment 5:**

**Template for Debriefing When Research Involves Deception**

Deception is providing to the participants incomplete or misleading information regarding the study procedures, purpose or intent. This is most often done in a designed attempt to eliminate participant response bias. It includes any communication to participants that intentionally creates a failure to obtain fully informed consent.

Please use the guidelines below to complete a “Debriefing Report” for your study participants when research uses deception and submit this with the research application. Write this with the study participant in mind as the target audience.

* + - 1. **Title of Research Study**
      2. **Purpose and Design of Study**

Explain clearly the purpose and design of the study. Explain why it was necessary to include deception of subjects in the design. State clearly the hypothesis of the study.

**3. Justify the Use of Deception**

Describe clearly the deception used in the study and indicate why deception was necessary. Explain why alternatives to deception would fail to yield the data required. If the deception might contribute to misconceptions participants might have about their responses, provide feedback to correct those misconceptions.

**4. Summarize the Results and Findings**

If the debriefing is held immediately after the subject’s participation, describe expected results and findings.

**5. Summarize the Conclusions**

If the debriefing is held immediately after the subject’s participation, describe tentative conclusion based on expected results and findings.